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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

PURDUE PHARMACEUTICAL PRODUCTS L.P., PURDUE PHARMA L.P., AND TRANSCEPT PHARMACEUTICALS, INC., Plaintiffs, v. PAR PHARMACEUTICAL, INC., Defendant.	C.A. No. 2:12-cv-06738-JLL-MAH ***Document Filed Electronically***

DEFENDANT PAR PHARMACEUTICAL, INC.'S ANSWER, SEPARATE DEFENSES, AND COUNTERCLAIMS

Defendant Par Pharmaceutical, Inc. ("Par"), by and through its attorneys, for its Answer to the Complaint of Plaintiffs Purdue Pharmaceutical Products, L.P., Purdue Pharma, L.P., and Transcept Pharmaceuticals, Inc. (collectively "Plaintiffs"), hereby declares as follows:

The Parties

1. Par is without knowledge and information sufficient to form a belief as to the location of organization and existence, and principal place of business of Purdue Pharmaceuticals Products, L.P. Par thus denies the allegations of Paragraph 1.

2. Par is without knowledge and information sufficient to form a belief as to the location of organization and existence, and principal place of business of Purdue Pharma L.P. Par thus denies the allegations of Paragraph 2.

3. Par is without knowledge and information sufficient to form a belief as to the location of incorporation and place of business of Transcept Pharmaceuticals, Inc. Par thus denies the allegations of Paragraph 3.

4. Par admits it is a corporation organized and existing under the laws of Delaware. Par avers that its principal place of business is located at 300 Tice Boulevard, Woodcliff Lake, New Jersey 07677.

5. Par admits that it is engaged in the manufacturing of, *inter alia*, generic pharmaceutical products in the United States, including in the District of New Jersey. Par admits that it has at least one place of business in New Jersey. Par admits that it is registered to do business in New Jersey under Business Entity I.D. No. 0100071541. Par further admits that it is a registered manufacturer and wholesaler of drugs with the New Jersey Department of Health under Registration No. 5004032. Par avers that Registration No. 5001143 is inactive. Par denies the remaining allegations of Paragraph 5.

Jurisdiction and Venue

6. Par admits that the Complaint purports to be a civil action for patent infringement under the patent laws of the United States, Title 35 of the United States Code, of U.S. Patent Nos. 8,242,131 (the "'131 patent") and 8,252,809 (the "'809 patent").

7. Paragraph 7 states a legal conclusion to which no response is required. To the extent a response is required, Par admits that Plaintiffs purport to base subject matter jurisdiction on 28 U.S.C. §§ 1331 and 1338(a). Par denies that it engaged in or is engaging in any act that violates the patent laws of the United States, and Par further denies that it engaged in or is engaging in any act resulting in liability for patent infringement.

8. Paragraph 8 state a legal conclusion to which no response is required. To the extent a response is required, Par states, for the limited purposes of this action only, that it does not contest personal jurisdiction in this judicial district.

9. Paragraph 9 states a legal conclusion to which no response is required. To the extent a response is required, Par admits that it has previously been a party to several cases unrelated to the instant dispute before this Court, including those listed in Paragraph 9, and that it has filed counterclaims in those cases. Par denies the remaining allegations of Paragraph 9.

10. Paragraph 10 states a legal conclusion to which no response is required. To the extent a response is required, Par admits that Plaintiffs purport to base venue on 28 U.S.C. §§ 1391 and 1400(b). Par does not contest venue in this judicial district for the limited purpose of this action only. Par denies the remaining allegations of Paragraph 10.

Regulatory Requirements for New and Generic Drugs

11. Paragraph 11 states a legal conclusion to which no response is required. To the extent a response is required, Par admits that 21 U.S.C. § 355(a) provides, *inter alia*, that "[n]o person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug." *Id.* Par also admits that a person seeking FDA approval of an application filed pursuant to 21 U.S.C. § 355(b) "shall submit to the Secretary as a part of the

application (A) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use . . . .” *Id.* § 355(b)(1).

12. Paragraph 12 states legal conclusions to which no response is required. To the extent a response is required, Par admits that 21 U.S.C. § 355(j) provides, *inter alia*, that “[a]ny person may file with the Secretary an abbreviated application for the approval of a new drug.” *Id.* § 355(j)(1). Par also admits that a person seeking FDA approval of an application filed pursuant to 21 U.S.C. § 355(j) must submit an application that contains “information to show that the new drug is bioequivalent to the listed drug . . . .” *Id.* § 355(j)(2)(A)(iv).

13. Paragraph 13 states legal conclusions to which no response is required. To the extent a response is required, Par admits that 21 U.S.C. § 355(j) does not provide that an applicant of an Abbreviated New Drug Application (“ANDA”) must include safety and effectiveness data in its application.

14. Paragraph 14 states legal conclusions to which no response is required. To the extent a response is required, Par admits that 21 U.S.C. § 355(j)(2)(A)(i) provides, *inter alia*, that an ANDA shall contain “information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a drug listed under paragraph (7) (hereinafter in this subsection referred to as a ‘listed drug’).” *Id.*

The Approved Drug Product

15. Par admits that New Drug Application (“NDA”) No. 022328 relates to sublingual tablets containing 1.75 mg and 3.5 mg of zolpidem tartrate. Par admits that according to the “Approved Drug Products with Therapeutic Equivalence Evaluations” (the “Orange Book”) listing of United States Food and Drug Administration (“FDA”), NDA No. 022328 was first

approved on November 23, 2011. Par admits that Purdue Pharma L.P. markets sublingual tablets containing 1.75 mg and 3.5 mg of zolpidem tartrate under the tradename INTERMEZZO. Par admits that what appears to be a copy of the prescribing information for INTERMEZZO is attached as Exhibit A to the Complaint. Par further admits that Exhibit A states that INTERMEZZO is "indicated for use as needed for the treatment of insomnia when a middle-of-the-night awakening is followed by difficulty returning to sleep." Par avers that according to the Orange Book, Purdue Pharma is the holder of NDA No. 022328. Par is without knowledge and information sufficient to admit or deny the remaining allegations of Paragraph 15 and thus denies the same.

16. Par admits that the '131 patent and the '809 patent are listed in the Orange Book with respect to NDA No. 022328.

17. Par admits that on its face, the '131 and '809 patent each identifies Transcept Pharmaceuticals, Inc. as its assignee. Par is without knowledge and information sufficient to admit or deny the remaining allegations of Paragraph 17 and thus denies the same.

ANDA No. 204229

18. Par admits that it submitted on or before September 10, 2012 an ANDA, assigned number 204229, to the FDA for 1.75 mg and 3.5 mg zolpidem tartrate sublingual tablets. Par admits that its purpose in submitting ANDA No. 204229 is to obtain approval under Section 505(j) of the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture and sale of 1.75 mg and 3.5 mg zolpidem tartrate sublingual tablets (hereinafter referred to as the "ANDA Products"). Par further admits that ANDA No. 204229 contained certifications under 21 U.S.C. 355(j)(2)(A)(vii)(IV) ("Paragraph IV certifications").

19. Par admits that the proposed labeling submitted in ANDA No. 204229 indicated that the ANDA Products are for the treatment of insomnia when middle-of-the-night awakening is followed by difficult returning to sleep, *i.e.*, the same indication as that set forth in the FDA-approved labeling for INTERMEZZO.

20. Par admits that it sent to Purdue Pharmaceutical Products L.P. and Transcept Pharmaceuticals, Inc. a notice letter dated September 10, 2012. Par admits that this notice letter represented that Par had filed with the FDA ANDA No. 204229 containing Paragraph IV certifications for the '131 and '809 patents. Par avers this notice letter advised Purdue Pharmaceutical Products L.P. and Transcept Pharmaceuticals, Inc. that the claims of the '131 and '809 patents are invalid, unenforceable, and/or will not be infringed by the ANDA Products.

21. Par admits that its purpose in submitting ANDA No. 204229 to the FDA is to obtain approval to market the ANDA Products, before the stated expiration of the '131 and '809 patents as listed in the Orange Book. Par denies the remaining allegations of Paragraph 21.

Count 1: Patent Infringement of the '131 Patent[1]

22. No response is required to the general reallegation and incorporation by reference of the allegations of Paragraphs 1-21 of the Complaint. To the extent a response is required, Par hereby incorporates by reference its responses to Paragraphs 1 through 21.

23. Par admits that the '131 patent, on its face, is entitled "Methods of Treating Middle-of-the-Night Insomnia" and lists its date of issue as August 14, 2012. Par admits that what appears to be a copy of the '131 patent is attached to the Complaint as Exhibit B. Par further admits that the '131 patent, on its face, identifies Transcept Pharmaceuticals, Inc. as its assignee. Par denies that the United States Patent and Trademark Office duly and legally issued

[1] Headings are reprinted here with the same language as used in Plaintiffs' Complaint simply for ease of reference, and do not constitute an admission.

the ’131 patent. Par is without knowledge and information sufficient to admit or deny the remaining allegations of Paragraph 23 and thus denies the same.

24. Par admits that it filed ANDA No. 204229 with the FDA to obtain approval to engage in the commercial manufacture, use, offer for sale, and sale of the ANDA Products, before the stated expiration of the ’131 patent as listed in the Orange Book.

25. Par denies the allegations of Paragraph 25.

26. Par admits that if the ANDA products are approved, Par will seek to market the ANDA products for the treatment of insomnia when middle-of-the-night awakening is followed by difficulty returning to sleep. Par denies the remaining allegations of Paragraph 26.

27. Par denies the allegations of Paragraph 27.

28. Par admits that it provided written certification to the FDA that the claims of the ’131 patent are invalid and/or will not be infringed by the manufacture, use, and/or sale of the ANDA Products.

29. Par admits that its notice letter dated September 10, 2012 sent to Purdue Pharmaceutical Products L.P. and Transcept Pharmaceuticals, Inc. contained a certification, which advised that all claims of the ’131 patent are invalid, and that Par seeks FDA’s approval to engage in the commercial manufacture, use, and sale of the ANDA products before the stated expiration of the ’131 patent. Par denies the remaining allegations of Paragraph 29.

30. Par denies the allegations of Paragraph 30.

31. Par denies the allegations of Paragraph 31.

32. Par denies the allegations of Paragraph 32.

Count 2: Patent Infringement of the '809 Patent

33. No response is required to the general reallegation and incorporation by reference of the allegations of Paragraphs 1-32 of the Complaint. To the extent a response is required, Par hereby incorporates by reference its responses to Paragraphs 1 through 32.

34. Par admits that the '809 patent, on its face, is entitled "Compositions for Treating Insomnia" and lists its date of issue as August 28, 2012. Par admits that what appears to be a copy of the '809 patent is attached to the Complaint as Exhibit C. Par further admits that the '809 patent, on its face, identifies Transcept Pharmaceuticals, Inc. as its assignee. Par denies that the United States Patent and Trademark Office duly and legally issued the '809 patent. Par is without knowledge and information sufficient to admit or deny the remaining allegations of Paragraph 34 and thus denies the same.

35. Par admits that it filed ANDA No. 204229 with the FDA to obtain approval to engage in the commercial manufacture, use, offer for sale, and sale of the ANDA Products, before the stated expiration of the '809 patent as listed in the Orange Book.

36. Par denies the allegations of Paragraph 36.

37. Par admits that if the ANDA products are approved, Par will seek to market the ANDA products for the treatment of insomnia when middle-of-the-night awakening is followed by difficulty returning to sleep. Par denies the remaining allegations of Paragraph 37.

38. Par denies the allegations of Paragraph 38.

39. Par admits that it provided written certification to the FDA that the claims of the '809 patent are invalid and/or will not be infringed by the manufacture, use, and/or sale of the ANDA Products.

40. Par admits that its notice letter dated September 10, 2012 sent to Purdue Pharmaceutical Products L.P. and Transcept Pharmaceuticals, Inc. contained a certification, which advised that all claims of the '809 patent are invalid, and that Par seeks FDA's approval to engage in the commercial manufacture, use, and sale of the ANDA products before the stated expiration of the '809 patent. Par denies the remaining allegations of Paragraph 40.

41. Par denies the allegations of Paragraph 41.

42. Par denies the allegations of Paragraph 42.

43. Par denies the allegations of Paragraph 43.

ANSWER TO PLAINTIFFS' PRAYER FOR RELIEF

Par denies that Plaintiffs are entitled to the relief they seek in Paragraphs A–G or any relief at all for the allegations made in the Complaint.

SEPARATE DEFENSES

Par pleads the following defenses in response to Plaintiffs' allegations, undertaking the burden of proof only as to those defenses deemed affirmative defenses by law, regardless of how such defenses are denominated herein. Par reserves the right to allege additional defenses in the event that discovery or other analysis indicates that additional affirmative or other defenses are appropriate.

FIRST SEPARATE DEFENSE

44. Each purported claim for relief in the Complaint is barred for failure to state a claim upon which relief can be granted.

SECOND SEPARATE DEFENSE

45. The claims of the '131 and '809 patents are invalid for failing to meet one or more requirements for patentability under Title 35 of the United States Code.

THIRD SEPARATE DEFENSE

46. The manufacture, use, sale, offer for sale, and/or importation into the United States of the ANDA Products does not and will not infringe, induce infringement of, or contribute to the literal infringement of any valid or enforceable claim of the '131 and '809 patents.

47. The manufacture, use, sale, offer for sale, and/or importation into the United States of the ANDA Products does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '131 and '809 patents under the doctrine of equivalents.

FOURTH SEPARATE DEFENSE

48. Par's actions in defending this case do not constitute an exceptional case under 35 U.S.C. § 285.

RESERVATION OF ADDITIONAL SEPARATE DEFENSES

Par reserves the right to assert additional defenses in the event that discovery or other analysis indicates that additional affirmative defenses are appropriate.

COUNTERCLAIMS

Counterclaimant Par Pharmaceutical Inc. asserts the following counterclaims against Purdue Pharmaceutical Products, L.P., Purdue Pharma, L.P., and Transcept Pharmaceuticals, Inc., (collectively "Plaintiffs") that U.S. Patent Nos. 8,242,131 (the "'131 patent") and 8,252,809 (the "'809 patent") are not infringed by the products described in ANDA No. 204229, and/or are invalid for violation of one or more provisions of Title 35 of the United States Code, including 35 U.S.C. § 101 *et seq*.

THE PARTIES

1. Defendant/Counterclaimant Par Pharmaceutical, Inc. is a corporation organized and existing under the laws of Delaware with a principal place of business at 300 Tice Boulevard, Woodcliff Lake, New Jersey 07677.

2. On information and belief, and based on Plaintiffs' allegations, Counterclaim-Defendant/Plaintiff Purdue Pharmaceutical Products L.P. is a limited partnership organized and existing under the laws of Delaware with its principal place of business at One Stamford Forum, 201 Tresser Boulevard, Stamford, Connecticut 06901.

3. On information and belief, and based on Plaintiffs' allegations, Counterclaim-Defendant/Plaintiff Purdue Pharma L.P. is a limited partnership organized and existing under the laws of Delaware with its principal place of business at One Stamford Forum, 201 Tresser Boulevard, Stamford, Connecticut 06901.

4. On information and belief, and based on Plaintiffs' allegations, Counterclaim-Defendant/Plaintiff Transcept Pharmaceuticals, Inc. is a corporation organized and existing under the laws of Delaware with its principal place of business at 1003 W. Cutting Boulevard, Suite 110, Pt. Richmond, California 94804.

NATURE OF THE ACTION

5. These claims arise under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Par Pharmaceutical, Inc. seeks declaration that the '131 and '809 patents are not infringed by the products described in Par Pharmaceutical, Inc.'s Abbreviated New Drug Application ("ANDA") No. 204229 and/or are invalid for failure to comply with one or more provisions of Title 35 of the United States Code, including 35 U.S.C. § 101 *et seq.*

JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction over these Counterclaims for declaratory judgment pursuant to 28 U.S.C. §§ 1331, 1337(a), 1338(a), 2201(a) and (b), and 2202 based on an actual controversy between Par Pharmaceutical, Inc. and Plaintiffs, arising under the patent laws of the United States, 35 U.S.C. §1 *et seq*. This Court has original jurisdiction over the subject matter of these claims under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202 as well as 21 U.S.C. § 355(c)(3)(D).

7. This Court has personal jurisdiction over Plaintiffs based on, *inter alia*, Plaintiffs' filing of this lawsuit in this jurisdiction.

8. Venue is proper in this judicial district based on 28 U.S.C. § 1400(a) and/or 28 U.S.C. § 1391(b), (c), and (d).

BACKGROUND

9. The '131 patent, on its face, is titled "Methods of Treating Middle-of-the-Night Insomnia" and states its date of issue as August 14, 2012.

10. The '809 patent, on its face, is titled "Compositions for Treating Insomnia" and states its date of issue as August 28, 2012.

11. On information and belief, and based on Plaintiffs' allegations, the '131 and '809 patents are owned by Transcept Pharmaceuticals, Inc.

12. On information and belief, and based on Plaintiffs' allegations, Purdue Pharmaceutical Products L.P. is the holder of New Drug Application ("NDA") No. 022328 for sublingual tablets containing zolpidem tartrate, sold in the United States as INTERMEZZO.

13. On information and belief, the United States Food and Drug Administration ("FDA") approved NDA No. 022328 on November 23, 2011.

14. Par Pharmaceutical, Inc. submitted ANDA No. 204229 to the FDA, requesting approval to engage in the commercial manufacture, use, importation, sale, and/or offer for sale in the United States of sublingual tablets containing zolpidem tartrate at 1.75 mg and 3.5 mg dosage strengths, before the stated expiration of the '131 and '809 patents. Par Pharmaceutical, Inc. made certifications under 21 U.S.C. § 355(j)(2)(a)(vii)(IV) ("Paragraph IV Certifications") that no valid or enforceable claim of the '131 and '809 patents would be infringed by the commercial manufacture, use, importation, sale, and/or offer for sale of the products that are the subject of ANDA No. 204229 (the "ANDA Products").

15. On October 25, 2012, Plaintiffs filed their Complaint alleging infringement by Par Pharmaceutical, Inc. of the '131 and '809 patents.

COUNT I
(Declaration of Invalidity of the '131 Patent)

16. Par Pharmaceutical, Inc. incorporates by reference Paragraphs 1 through 15 of its Counterclaims as if fully set forth herein.

17. The claims of the '131 patent are invalid for failing to meet one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. § 101 *et seq.*

18. A definite and concrete, real and substantial, justiciable controversy exists between Par Pharmaceutical, Inc. and Plaintiffs concerning the validity of the '131 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

19. Par Pharmaceutical, Inc. is entitled to a judicial declaration that the '131 patent is invalid.

COUNT II
(Declaration of Noninfringement of the ’131 Patent)

20. Par Pharmaceutical, Inc. incorporates by reference Paragraphs 1 through 19 of its Counterclaims as if fully set forth herein.

21. The manufacture, use, sale, offer for sale, and/or importation into the United States of the ANDA Products does not and will not literally infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the ’131 patent.

22. The manufacture, use, sale, offer for sale, and/or importation into the United States of the ANDA Products does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the ’131 patent under the doctrine of equivalents.

23. A definite and concrete, real and substantial, justiciable controversy exists between Par Pharmaceutical, Inc. and Plaintiffs concerning the alleged infringement by the ANDA Products of the ’131 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

24. Par Pharmaceutical, Inc. is entitled to a judicial declaration that the ’131 patent is not infringed.

COUNT III
(Declaration of Invalidity of the ’809 Patent)

25. Par Pharmaceutical, Inc. incorporates by reference Paragraphs 1 through 24 of its Counterclaims as if fully set forth herein.

26. The claims of the ’809 patent are invalid for failing to meet one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. § 101 *et seq.*

27. A definite and concrete, real and substantial, justiciable controversy exists between Par Pharmaceutical, Inc. and Plaintiffs concerning the validity of the ’809 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

28. Par Pharmaceutical, Inc. is entitled to a judicial declaration that the ’809 patent is invalid.

COUNT IV
(Declaration of Noninfringement of the ’809 Patent)

29. Par Pharmaceutical, Inc. incorporates by reference Paragraphs 1 through 28 of its Counterclaims as if fully set forth herein.

30. The manufacture, use, sale, offer for sale, and/or importation into the United States of the ANDA Products does not and will not literally infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the ’809 patent.

31. The manufacture, use, sale, offer for sale, and/or importation into the United States of the ANDA Products does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the ’809 patent under the doctrine of equivalents.

32. A definite and concrete, real and substantial, justiciable controversy exists between Par Pharmaceutical, Inc. and Plaintiffs concerning the alleged infringement by the ANDA Products of the ’809 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

33. Par Pharmaceutical, Inc. is entitled to a judicial declaration that the ’809 patent is not infringed.

PRAYER FOR RELIEF

WHEREFORE, Par Pharmaceutical, Inc. requests the following relief:

a) Dismissing Plaintiffs' Complaint with prejudice and denying each request for relief made by Plaintiffs;

b) Declaring all claims of the '131 patent invalid;

c) Declaring all claims of the '131 patent not infringed by the making, use, sale, offer for sale, marketing, or importation into the United States of the ANDA Products;

d) Declaring all claims of the '809 patent invalid;

e) Declaring all claims of the '809 patent not infringed by the making, use, sale, offer for sale, marketing, or importation into the United States of the ANDA Products;

f) That the 30-month time period referred to within 21 U.S.C. § 355(j)(5)(B)(iii) be shortened to expire immediately;

g) Declaring that this is an exceptional case under 35 U.S.C. § 285 and awarding Par Pharmaceutical, Inc. its attorneys' fees, costs, and expenses in this action; and

h) Awarding Par Pharmaceutical, Inc. such other and further relief as the Court deems just and proper.

Dated: December 20, 2012

Respectfully submitted,

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Attorneys for Defendant/Counterclaimant
Par Pharmaceutical, Inc.

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LOCAL CIVIL RULE 11.2 CERTIFICATION

Under Local Civil Rule 11.2, the undersigned counsel for Defendant/Counterclaimant Par Pharmaceutical, Inc. ("Par") hereby certifies that United States Patent Nos. 8,242,131 and 8,252,809 are also the subject of litigation in *Purdue Pharmaceutical Products L.P., et al. v. Par Formulations Private LTD.*, Civil Action No. 2:12-cv-06741-JLL-MAH (D.N.J.).

Dated: December 20, 2012

/s/ Sean R. Kelly
Sean R. Kelly

LOCAL CIVIL RULE 201.1 CERTIFICATION

Pursuant to Local Civil Rule 201.1, the undersigned counsel for Par hereby certifies that Par seeks declaratory relief, and therefore this action is not appropriate for compulsory arbitration.

Dated: December 20, 2012

/s/ Sean R. Kelly
Sean R. Kelly